

SINOSIL NASAL DECONGESTANT- xylometazoline hcl spray
Herbion Pakistan Pvt Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Xylometazoline HCl 0.1%

Nasal Decongestant

Temporarily relieves nasal congestion due to cold, hay fever or other respiratory allergies.

Do not exceed recommended dose.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.
- This product may cause temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge.
- The use of this container by more than one person may spread infection.

Stop use and ask a doctor if symptoms persist.

If pregnant or breast feeding, consult your physician before using.

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 12 years of age and over: 2 or 3 sprays in each nostril not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

Store at 20-25 degrees C (68-77 degrees F)

Disodium edetate, Di-sodium hydrogen phosphate, D.I. Water, Sodium Chloride, Sodium di-hydrogen phosphate, thiomersal

Questions or comments?

1-888-654-3724, Monday through Friday, 9am-5pm or www.herbion.com

Nasal Decongestant Spray

For temporary decongestion of the nasal mucosa

27.01.11 USA

W 45 MM

For temporary decongestion of the nasal mucosa
Nasal Decongestant Spray

Xylometazoline HCL
SINOSIL



H 27 MM

SINOSIL

Xylometazoline HCL

Nasal Decongestant Spray

For temporary decongestion of the nasal mucosa

0.51 fl oz (15 ml)

Drug Facts

Active Ingredients	Purpose
Xylometazoline HCl 0.1%.....	Nasal Decongestant

Uses
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Directions
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**(Continued on other side)*

SINOSIL

Xylometazoline HCL

Nasal Decongestant Spray

For temporary decongestion of the nasal mucosa

0.51 fl oz (15 ml)

Drug Facts (Continued)

Other Information
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Inactive Ingredients:
Disodium edentate, Di-Sodium hydrogen phosphate, D.I Water, Sodium Chloride, Sodium di-hydrogen phosphate, Thiomersal

Questions or comments?
1-888-654-3724, Monday through Friday, 9am - 5pm or www.herbion.com

Batch No.
Mfg. Date.
Expiry Date.

Manufactured for:
Herbion USA Inc.
Williamsville, NY 14221
info.us@herbion.com
www.herbion.com



Made in Pakistan

H 90 MM

W 45 MM

W 27 MM

USA

SINOSIL NASAL DECONGESTANT

xylometazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-007
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
XYLOMETAZOLINE HYDROCHLORIDE (UNII: X5S84033NZ) (XYLOMETAZOLINE - UNII: WPY40FTH8K)	XYLOMETAZOLINE HYDROCHLORIDE	.015 mL in 15 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
THIMEROSAL (UNII: 2225PI3MOV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-007-15	15 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/09/2011	

Labeler - Herbion Pakistan Pvt Ltd (645482936)**Registrant** - Herbion Pakistan Pvt Ltd (645482936)**Establishment**

Name	Address	ID/FEI	Business Operations
Herbion Pakistan Pvt Ltd		645482936	manufacture

Revised: 2/2011

Herbion Pakistan Pvt Ltd